Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

**Page:** 93

Report Date: 06/05/2013

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Study Summary**

Vehicle: WATER

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory Battelle Columbus Laboratory	052000506 052020304	02/10/04 07/10/07	730 730	50(1) 50(1)	32(691) 33(694)	51.1 52.6	Ginseng Green tea extract
					Female		
Battelle Columbus Laboratory Battelle Columbus Laboratory	052000506 052020304	02/09/04 07/09/07	729 729	50(5) 50(5)	38(711) 34(665)	63.9 62.9	Ginseng Green tea extract

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 94

			Male				Female	
#All Organs: Benign Tumors				,				
		38/50 (76%)	43/50 (86%)			33/50 (66%)	20/50 (40%)	
Overall Incidence	Total	81/100 (81%)	Mean 81%	SD 7.07%	Total	53/100 (53%)	Mean 53%	SD 18.38%
#All Organs: Malignant Tumors								
		26/50 (52%)	28/50 (56%)			15/50 (30%)	18/50 (36%)	
Overall Incidence	Total	54/100 (54%)	Mean 54%	SD 2.83%	Total	33/100 (33%)	Mean 33%	SD 4.24%
#All Organs: Malignant and Benign Tu	umors	46/50 (92%)	49/50 (98%)			42/50 (84%)	29/50 (58%)	
Overall Incidence	Total	95/100 (95%)	Mean 95%	SD 4.24%	Total	71/100 (71%)	Mean 71%	SD 18.38%
All Organs: Hemangioma		1/50 (2%)	2/50 (4%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#All Organs: Hemangiosarcoma								
-		4/50 (8%)	5/50 (10%)			0/50 (0%)	2/50 (4%)	
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#All Organs: Hemangiosarcoma or He	emangioma							
		5/50 (10%)	7/50 (14%)			1/50 (2%)	2/50 (4%)	
Overall Incidence	Total	12/100 (12%)	Mean 12%	SD 2.83%	Total	3/100 (3%)	Mean 3%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 95

			Male				Female	
#All Organs: Histiocytic Sarcoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
			ivican 170		10tai			
#All Organs: Malignant Lymphoma: Histic	ocytic, Lym			I Туре				
		4/50 (8%)	4/50 (8%)			9/50 (18%)	7/50 (14%)	
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 0%	Total	16/100 (16%)	Mean 16%	SD 2.83%
#All Organs: Mesothelioma: Benign								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign, Mali						0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant								
O	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma		0/50 (00/)	0/50 (00)			0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 00/	Total	0/50 (0%)	0/50 (0%)	SD 00/
Overall incidence	Total	0/100 (0%)	iviean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 96

			Male				Female	
#All Organs: Osteosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteoma			- /					
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma								
		1/50 (2%)	1/49 (2%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%	Total	0/99 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Plasma Cell Tumor Malignar								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
	ı Olai			3D 0/0				
*Adrenal Medulla: Pheochromocytoma Benign								
		0/50 (0%)	0/49 (0%)			1/50 (2%)	0/49 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
*Adrenal Medulla: Pheochromocytoma Maligna	ınt							
		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 97

			Male				Female					
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS  0/50 (0%) 0/49 (0%)  1/50 (2%) 0/49 (0%)												
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%				
#Blood Vessel: Hemangioma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Bone Marrow: Hemangioma		0/50 (00/)										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Bone Marrow: Hemangiosarcoma		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Bone Marrow: Mast Cell Tumor Malignant												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Bone Marrow: Plasma Cell Tumor Malignar												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 98

			Male				Female	
*Bone Marrow: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Fibroma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Hemangiosarcoma			- /					
Occupation of the second	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Osteoma		0/50 (001)	2/52 (221)			0(70 (00))	(00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Bone: Osteosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Osteoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%
	Total	0/100 (0%)	Mean 0%		Total	0/100 (0%)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1 Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups Route: GAVAGE Vehicle: WATER

**Page**: 99

			Male				Female	
#Bone: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Ben	nign	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Benign						0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Meningioma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Ma	llignant, NOS	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Maliç	gnant	0/50 (00/)	0/50 (00)			0/50 (001)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 100

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Report	Date:	06/	05/	20	1
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			Male				Female					
*Brain: Oligodendroglioma, Glioma, or Astrocytoma  0/50 (0%) 0/50 (0%) 0/50 (0%)												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Brain: Schwannoma Malignant		0/50 (00/)	0/50 (00)			0/50 (00/)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Clitoral/Preputial Gland: Hemangioma		0/50 (0%)	0/50 (00/)			0/50 (00/)	0/40 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%				
·····		, ,				, ,						
*Clitoral/Preputial Gland: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%				
#Coagulating Gland: Granular Cell Tumor												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Coagulating Gland: Sarcoma												
Occupation of James	T-1-1	0/50 (0%)	1/50 (2%)	OD 4 440/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 101

			Male				Female	
#Esophagus: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Eye: Melanoma Malignant								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma								
		11/50 (22%)	7/50 (14%)			7/50 (14%)	2/50 (4%)	
Overall Incidence	Total	18/100 (18%)	Mean 18%	SD 5.66%	Total	9/100 (9%)	Mean 9%	SD 7.07%
#Harderian Gland: Carcinoma								
	<b>-</b>	1/50 (2%)	1/50 (2%)	00.00/	<b></b>	0/50 (0%)	2/50 (4%)	00.000/
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#Harderian Gland: Carcinoma or Adenoma								
		12/50 (24%)	8/50 (16%)			7/50 (14%)	4/50 (8%)	
Overall Incidence	Total	20/100 (20%)	Mean 20%	SD 5.66%	Total	11/100 (11%)	Mean 11%	SD 4.24%
*Heart: Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 102

			Male				Female	
#Intestine Large: Cecum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma or Adenoma								
Occupation of the second	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyoma								
Occupation of James	Taral	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rect Leiomyosarcoma	um:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 103

		Male				Female	
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	` '	, ,			` ,	` '	
	, ,				, ,		SD 0%
	0/50 (001)	0/50 (00/)			0/50 (00/)	0/50 (00)	
Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	` '	` ,	SD 0%	Total	` ,	` '	SD 0%
	Total  Total	Total 0/100 (0%)  0/50 (0%)  Total 0/100 (0%)  0/50 (0%)  Total 0/100 (0%)  Total 0/50 (0%)  Total 0/100 (0%)	Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%)  Total 0/100 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%	Total 0/100 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%  Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%  Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%	Total         0/100 (0%)         Mean 0%         SD 0%         Total           0/50 (0%)         0/50 (0%)         0/50 (0%)         Total           Total         0/100 (0%)         0/50 (0%)         SD 0%         Total           Total         0/100 (0%)         0/50 (0%)         SD 0%         Total           Total         0/100 (0%)         0/50 (0%)         SD 0%         Total           Total         0/50 (0%)         0/50 (0%)         SD 0%         Total           Total         0/100 (0%)         0/50 (0%)         SD 0%         Total           Total         0/100 (0%)         0/50 (0%)         SD 0%         Total	Total         0/100 (0%)         Mean 0%         SD 0%         Total         0/100 (0%)           0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)           Total         0/100 (0%)         0/50 (0%)         0/50 (0%)	Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  O/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  O/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  O/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 104

			Male				Female	
#Intestine Small: Ileum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)	05.00		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	25 22/		0/50 (0%)	0/50 (0%)	00.007
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Site Unspec Adenoma	cified:							
		0/50 (0%)	0/50 (0%)	25 22/		0/50 (0%)	0/50 (0%)	<b>05</b>
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 105

			Male				Female	
#Intestine Small: Site Unsp	ecified:							
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Carcinoma or Adenoma	ecified:							
		0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Site Unsp	ecified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
		1/50 (2%)	1/50 (2%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 106

			Male				Female	
*Islets, Pancreatic: Carcinoma								
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma								
		2/50 (4%)	2/50 (4%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 0%
*Kidney: Pelvis and Transitio Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Pelvis and Transitio Carcinoma or Adenoma		m:				- ()	2(-2)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma		(Jan (Jan))				0.000	(00)	
		1/50 (2%)	2/50 (4%)	<b>25</b>		0/50 (0%)	0/50 (0%)	05 00/
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 107

			Male				Female	
*Kidney: Renal Tubule: Carcinoma or Adenoma		1/50 (2%)	3/50 (6%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma							•••••	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Kidney: Renal Tubule: Plasma Cell Tumor Maligna	ınt	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Liver: Hemangioma								
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 108

			Male				Female	
*Liver: Hemangiosarcoma								
		2/50 (4%)	3/50 (6%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Liver: Hepatoblastoma								
		1/50 (2%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma		24/50 (690/)	25/50 /709/\			24/50 (420()	42/50 (249/)	
Overall Incidence	Total	34/50 (68%) 69/100 (69%)	35/50 (70%) Mean 69%	SD 1.41%	Total	21/50 (42%) 33/100 (33%)	12/50 (24%) Mean 33%	SD 12.73%
	10tai	09/100 (09/0)	······································					
*Liver: Hepatocellular Carcinoma								
Overell Incidence	Tatal	14/50 (28%)	15/50 (30%)	CD 4 440/	Tatal	2/50 (4%)	5/50 (10%)	CD 4.040/
Overall Incidence	Total	29/100 (29%)	Mean 29%	SD 1.41%	Total	7/100 (7%)	Mean 7%	SD 4.24%
*Liver: Hepatocellular Carcinoma o	or Hepatobl	astoma						
-	-	14/50 (28%)	17/50 (34%)			2/50 (4%)	5/50 (10%)	
Overall Incidence	Total	31/100 (31%)	Mean 31%	SD 4.24%	Total	7/100 (7%)	Mean 7%	SD 4.24%
*Liver: Hepatocellular Carcinoma o	or Hepatoce		40/50 (00%)			20/50 (469()	44/50 (000)	
Overall Incidence	Total	39/50 (78%) 79/100 (79%)	40/50 (80%) Mean 79%	SD 1.41%	Total	23/50 (46%) 37/100 (37%)	14/50 (28%) Mean 37%	SD 12.73%
		79/100 (79%)				` '		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 109

			Male				Female				
*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma 39/50 (78%) 40/50 (80%) 23/50 (46%) 14/50 (28%)											
Overall Incidence	Total	79/100 (79%)	Mean 79%	SD 1.41%	Total	37/100 (37%)	Mean 37%	SD 12.73%			
*Liver: Hepatocholangiocarcinom											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Liver: Hepatocholangioma											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Liver: Ito Cell Tumor Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
*Liver: Mast Cell Tumor Malignan			0/50 (0%)			0/50 (0%)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
*Liver: Plasma Cell Tumor Malign	ant	0/50 (00)	0/50 (000)			0/50 (00)	0/50 /00/				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 110

			Male				Female	
*Liver: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Ad	denoma							
		9/50 (18%)	12/50 (24%)			6/50 (12%)	5/50 (10%)	
Overall Incidence	Total	21/100 (21%)	Mean 21%	SD 4.24%	Total	11/100 (11%)	Mean 11%	SD 1.41%
*Lung: Alveolar/Bronchiolar Ca	arcinoma	2/52 (694)	0/50 /40/			4/50 (001)	4/50 (00)	
Overall Incidence	Total	3/50 (6%) 5/100 (5%)	2/50 (4%) Mean 5%	SD 1.41%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
*Lung: Alveolar/Bronchiolar Ca Overall Incidence	arcinoma or Alv Total	eolar/Bronchiolar Adenor 12/50 (24%) 26/100 (26%)	<b>na</b> 14/50 (28%) Mean 26%	SD 2.83%	Total	7/50 (14%) 13/100 (13%)	6/50 (12%) Mean 13%	SD 1.41%
*Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Lung: Plasma Cell Tumor Mali	ignant	0/50 (00)	0/50 /00/			0/50 (00/)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		0/100 (0%)				` ,	IVICALI U%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 111

		Male				Female					
#Lymph Node: Plasma Cell Tumor Malignant  0/50 (0%) 0/50 (0%)  0/50 (0%)  0/50 (0%)											
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
<b>-</b>	` '	` '	00.00/	<b>-</b>	` ,	` '	00.00/				
l otal	0/100 (0%)	Mean 0%	SD 0%	ı otal	0/100 (0%)	Mean 0%	SD 0%				
nt	1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
nant											
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
nt	0/50 (0%)	0/50 (00/)			0/50 (09/\	0/50 (09/)					
Total	` '	` ,	SD 0%	Total	` '	` '	SD 0%				
	Total  Total  Total  Total  Total  Total	0/50 (0%) Total 0/100 (0%)  0/50 (0%)  Total 0/100 (0%)  Total 0/50 (0%)  Total 0/100 (0%)  1/50 (2%)  Total 1/100 (1%)  nant  0/50 (0%)  Total 0/100 (0%)	Total 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%  1/50 (2%) 0/50 (0%)  Total 1/100 (1%) Mean 1%  nant  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0%	Total 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0%     0/50 (0%) 0/50 (0%)   Total 0/100 (0%) Mean 0% SD 0%    Total 0/50 (0%) 0/50 (0%)   Total 0/100 (0%) Mean 0% SD 0%    1/50 (2%) 0/50 (0%)   Total 1/100 (1%) Mean 1% SD 1.41%    1/50 (2%) 0/50 (0%)   Total 0/100 (0%) Mean 1% SD 1.41%    Total 0/100 (0%) Mean 0% SD 0%	Total 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total  1/50 (2%) 0/50 (0%)  Total 1/100 (1%) Mean 1% SD 1.41% Total  nant  0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total	Total 0/50 (0%) 0/50 (0%) SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) 0/50 (0%) SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 1% SD 1.41% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)	Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 1/50 (2%) 0/50 (0%) SD 1.41% Total 0/100 (0%) Mean 0%  Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%) 0/50 (0%)				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 112

			Male				Female	
#Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Malignar	nt							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	25 22/		1/50 (2%)	0/50 (0%)	05
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	25 22/		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Mammary Gland: Fibroadenoma		- (ac)	(05.1)					
Overall Insidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 113

			Male				Female				
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma											
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
#Mammary Gland: Fibroma, Fibroadenoma	a, Carcinoma, or	Adenoma									
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
#Mesentery: Hemangioma		0/50 (0%)	0/50 (09/)			0/50 (00/)	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
		, ,									
#Mesentery: Hemangiosarcoma							- ()				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%			
	10tai	0/100 (0%)			10tai	0/100 (0%)	Mean 0%	3D 0%			
#Mesentery: Lipoma											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Mesentery: Sarcoma		- (ac)									
Overell healdenes	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 114

			Male				Female	
*Nose: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/48 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/98 (1.02%)	Mean 1.04%	SD 1.47%
*Nose: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o	sa, Tongue, Phary	ynx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Squamous Cell Carcine	sa, Tongue, Phary							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos	sa, Tongue, Phary		0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcin	oma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incidence	างเลเ	0/100 (0%)	iviean 0%	SD 0%	าบเลเ	0/100 (0%)	Mean 0%	3D 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 115

	Male			Female	
*Ovary: Choriocarcinoma			2/22 (221)	2/52 (22)	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Cystadenocarcinoma					
Overall Incidence		Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Ovary: Cystadenoma			<b>-</b> (-)	0.75	
Overall Incidence		Total	7/50 (14%) 10/100 (10%)	3/50 (6%) Mean 10%	SD 5.66%
*Ovary: Granulosa Cell Tumor Benign			(201)	(201)	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Hemangioma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

**Page:** 116

	Male			Female	
*Ovary: Hemangiosarcoma			2(72)	0.170 (001)	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Luteoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Plasma Cell Tumor Malignant			0/50 (00/)	0/50 (00())	
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Sarcoma					
Overall Incidence		Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Ovary: Teratoma Benign					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Teratoma Malignant					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 117

			Male		Female					
*Ovary: Tubulostromal Adenoma	a									
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Ovary: Yolk Sac Carcinoma										
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Pancreas: Carcinoma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Pancreas: Carcinoma or Adenoma										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Pituitary Gland: Pars Dist		ified Site:					•••••			
Overall Incidence	Total	1/50 (2%) 2/99 (2.02%)	1/49 (2%) Mean 2.02%	SD 0.03%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%		
*Pituitary Gland: Pars Dist		ified Site:								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 118

			Male				Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma												
		1/50 (2%)	1/49 (2%)			1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Pituitary Gland: Pars Inte Adenoma	ermedia:											
		0/50 (0%)	0/49 (0%)			1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Pituitary Gland: Pars Inte Carcinoma or Adenoma												
O	T-1-1	0/50 (0%)	0/49 (0%)	OD 00/	T-1-1	1/50 (2%)	0/50 (0%)	00 4 440/				
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Salivary Glands: Adenoma												
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Carcinoma or Adenoma	a											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Hemangiosarcoma			0.000			0.000						
O !!   ! .	Taral	0/50 (0%)	0/50 (0%)	OD 00/	Tatal	0/50 (0%)	0/50 (0%)	OD 00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 119

		Male				Female		
nt								
	1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Total	, ,			Total	0/100 (0%)	Mean 0%	SD 0%	
					0(50 (001)	0/50 (00/)		
Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
	0/50 (0%)	0/50 (0%)						
Total	0/50 (0%)	Mean 0%	SD 0%					
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
	0/50 (0%)	0/50 (0%)			0/50 (0%)	2/50 (4%)		
Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%	
habdomyoma	(20)				2(-2)			
Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	
	Total  Total  Total  Total  habdomyoma	1/50 (2%) Total 1/100 (1%)  0/50 (0%) Total 0/100 (0%)  Total 0/50 (0%)  Total 0/100 (0%)  Total 0/50 (0%)  Total 0/100 (0%)  Total 0/50 (0%)  Total 0/100 (0%)  habdomyoma  0/50 (0%)	1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  1 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  1 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  1 0/50 (0%) Mean 0%  1 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0%  1 0/50 (0%) 0/50 (0%)  1 0/50 (0%) 0/50 (0%)  1 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41%  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%  Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%  Total 0/100 (0%) Mean 0% SD 0%	Total 1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total  0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) 0/50 (0%) Total 0/50 (0%) Mean 0% SD 0%  Total 0/50 (0%) 0/50 (0%)	tt  1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%)  0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%)  Total 0/100 (0%) Mean 0% SD 0%  Total 0/100 (0%)	Total 1/50 (2%) 0/50 (0%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%  Total 0/100 (0%) 0/50 (0%)  Total 0/100 (0%) Mean 0% SD 0%  Total 0/100 (0%) Mean 0% SD 0%  Total 0/100 (0%) Mean 0% SD 0%  Total 0/100 (0%) Mean 0%  SD 0%  Total 0/100 (0%) 0/50 (0%) Mean 0%  SD 0%  Total 0/100 (0%) 0/50 (0%) Mean 0%  SD 0%  Total 0/100 (0%) 0/50 (0%) Mean 0%  SD 0%  Total 0/100 (0%) 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) 0/50 (0%) 0/50 (0%)  Total 0/100 (0%) 0/50 (0%) 0/50 (0%)	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1

#### **Toxicology Data Management System**

Page: 120

Report Date: 06/05/2013

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: WATER

Male **Female #Skeletal Muscle:** Sarcoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% SD 0% #Skin: **Basal Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total ...... #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma (2%)0/50 (0%)4/50 (8%)0/50 (0%)SD 1.41% SD 5.66% **Overall Incidence** Total 1/100 (1%) Mean 1% Total 4/100 (4%) Mean 4%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 121

			Male		Female						
#Skin: Fibrosarcoma											
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%			
#Skin:	M	as Filosopa Histia automa									
Fibrosarcoma, Sarcoma	, wyxosarcoma	, or Fibrous Histiocytoma 1/50 (2%)	0/50 (0%)			4/50 (8%)	0/50 (0%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	4/100 (4%)	Mean 4%	SD 5.66%			
#Skin: Fibrous Histiocytoma											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%			
#Skin: Granular Cell Tumor Bei	nign	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Hemangioma											
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Skin: Hemangiosarcoma		0/50 (00:)	0/50 (05)			0(50 (00))	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 122

			Male		Female				
#Skin: Keratoacanthoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%	
#Skin: Lipoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Skin: Liposarcoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Skin: Mast Cell Tumor Benign	••••••					0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Skin: Mast Cell Tumor Malignant									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Skin: Melanoma Benign		0/50 (00/)	0/50 (00/)			0/50 /00/	0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 123

(0%) 0/50 Mear (0%) 0/50 Mear (0%) 0/50 Mear	SD 0% Total  SD 0% Total  SD 0% Total	0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0%	SD 0% SD 0% SD 0%
(0%) 0/50 Mear	SD 0% Total	0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)  0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)	SD 0%
(0%) 0/50 Mear	SD 0% Total	0/50 (0%) 0/50 (0%) 0/100 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	SD 0%
Mear (0%) 0/50		0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)	
Mear (0%) 0/50		0/100 (0%) Mean 0%  0/50 (0%) 0/50 (0%)	
(0%) 0/50		0/50 (0%) 0/50 (0%)	
` '	SD 0% Total	. , , , , , , , , , , , , , , , , , , ,	SD 0%
` '	SD 0% Total	. , , , , , , , , , , , , , , , , , , ,	SD 0%
<b>6)</b> (2%) 0/50		2/50 (4%) 0/50 (0%)	
Mear	SD 1.41% Total	2/100 (2%) Mean 2%	SD 2.83%
enign, malignant or		2/50 (4%) 0/50 (0%)	
` '	SD 1.41% Total	2/100 (2%) Mean 2%	SD 2.83%
		0/50 (00() 0/50 (00()	
(00()		( )	SD 0%
	(2%) 0/50 (0%) Mean 1%  (0%) 0/50 (0%)	(2%) 0/50 (0%) Mean 1% SD 1.41% Total  (0%) 0/50 (0%)	(2%) 0/50 (0%) 2/50 (4%) 0/50 (0%)  Mean 1% SD 1.41% Total 2/100 (2%) Mean 2%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 124

			Male	Female					
#Skin: Sarcoma		200	2(72 (22))			2(72)	0.50		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Skin: Schwannoma Benign		0/50 (00/)	0/50 (00)			0(50 (00))	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
Skin: Schwannoma Malignant									
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	
#Skin: Squamous Cell Carcinom or Carcinoma	a, Basal Cell (	•		or NOS),		0/50 (00/)	0/50 (09/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
Skin: Squamous Cell Papilloma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
Skin:	or Papilloma					0/50 (0%)	0/50 (0%)		
Squamous Cen Fapinoma		0/50 (0%)	0/50 (0%)						

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 125

			Male				Female					
#Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Squamous Cell Papilloma	a, Papilloma, o	r Keratoacanthoma					•••••					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Sebaceous Gland: Adenoma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)				0/50 (0%)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Spinal Cord: Hemangiosarcoma												
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Spleen: Hemangioma			(00)			(20)						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 126

			Male		Female							
*Spleen: Hemangiosarcoma												
_		1/50 (2%)	2/50 (4%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Spleen: Mast Cell Tumor Malignan	t											
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
*Spleen: Plasma Cell Tumor Malign	ant	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Stomach, Forestomach: Squamous Cell Carcinoma	1	0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				
#Stomach, Forestomach: Squamous Cell Carcinoma			0/50 (0%)			0/50 (0%)	2/50 (4%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%				
#Stomach, Forestomach: Squamous Cell Papilloma		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	1/100 (1%)	0/30 (0%) Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 127

			Male				Female	
#Stomach, Glandular: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Testes: Adenoma  Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%				
·····		` '						
*Testes: Hemangioma								
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Thymus: Neoplasm NOS								
		0/47 (0%)	0/44 (0%)	05.00/		0/48 (0%)	0/47 (0%)	25.00/
Overall Incidence	Total	0/91 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 128

			Male				Female		
*Thymus: Thymoma Benign									
Overall Incidence	Total	0/47 (0%) 0/91 (0%)	0/44 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/95 (0%)	0/47 (0%) Mean 0%	SD 0%	
*Thymus: Thymoma Malignant		0/47 (0%)	0/44 (0%)			0/48 (0%)	0/47 (0%)		
Overall Incidence	Total	0/91 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma: Benign, Maligna	ant, NOS	0/47 (0%)	0/44 (0%)			0/48 (0%)	0/47 (0%)		
Overall Incidence	Total	0/91 (0%)	Mean 0%	SD 0%	Total	0/95 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma			0/50 (00/)				0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Thyroid Gland: Follicular Ce Adenoma	ell:	4/50 (00)	4/50 (004)				0/50 (00/)		
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 129

			Male				Female	
*Thyroid Gland: Follicular Ce Carcinoma	II:							
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Ce Carcinoma or Adenoma								
		1/50 (2%)	1/50 (2%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Tissue NOS: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	05.00/		0/50 (0%)	0/50 (0%)	05.00
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Plasma Cell Tumor Maligna	ant							
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 130

			Male				Female	
#Tongue: Fibroma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinom								
- 1		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Urethra: Hemangiosarcoma								
_		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 131

			Male				Female				
*Urinary Bladder: Plasma Cell Tumor Malignant  0/50 (0%) 0/50 (0%) 0/50 (0%)											
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%			
#Uterus: Adenoma											
						0/50 (0%)	0/50 (0%)				
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%			
#Uterus: Carcinoma											
						0/50 (0%)	0/50 (0%)				
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%			
#Uterus: Hemangiosarcoma						0/50 (00()	0/50 (00/)				
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Uterus: Leiomyoma											
•						0/50 (0%)	0/50 (0%)				
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%			
#Uterus: Leiomyosarcoma											
						0/50 (0%)	0/50 (0%)				
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 132

		Male				Female	
#Uterus: Polyp Stromal							
Overall Incidence				Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
#Uterus: Sarcoma							
Overall Incidence				Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal							
Overall Incidence				Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal					0/50 (00/)	0/50 (40/)	
Overall Incidence				Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
#Vagina: Liposarcoma						•••••	•••••
Overall Incidence				Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma					(20)		
Overall Incidence Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER **Page:** 133

			Male				Female	
#Zymbal's Gland: Carcinoma or Adenoma		2/22 (221)	2(72 (224)			2(22)	0.50	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied